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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 5

Completion if Known

Application Number 10/664,803
Filing Date September 19, 2003
First Named Inventor Unchalee Kositprapa
Art Unit
Examiner Name
Attorney Docket Number 141-424

U.S. PATENT DOCUMENTS

Examiner/Initials	Cite No.	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
7A.S./	AA	US-3,174,901		03-23-1965	Sterne	
	AB	US-3,960,949		06-01-1976	Ahrens et al.	
	AC	US-4,166,800		09-04-1979	Fong	
	AD	US-4,389,330		06-21-1983	Tice et al.	
	AE	US-4,687,777		08-18-1987	Meguro et al.	
	AF	US-4,839,177		06-13-1989	Colombo et al.	
	AG	US-4,891,223		01-02-1990	Ambegaonkar et al.	
	AH	US-4,968,507		11-06-1990	Zentner et al.	
	AI	US-5,294,770		03-15-1994	Riddle et al.	
	AJ	US-5,356,913		10-18-1994	Colca	
	AK	US-5,376,771		12-27-1994	Roy	
	AL	US-5,478,852		12-26-1995	Olefsky et al.	
	AM	US-5,602,133		02-11-1997	Antonucci et al.	
	AN	US-5,658,474		08-19-1997	Geerke	
	AO	US-5,681,584		10-28-1997	Savastano et al.	
	AP	US-5,698,220		12-16-1997	Cardinal et al.	
	AR	US-5,719,188		02-17-1998	Colca	
	AS	US-5,859,037		01-12-1999	Whitcomb	
7A.S./	AT	US-5,916,584		06-29-1999	O'Donoghue et al.	
	AT	US-5,952,356		09-14-1999	Ikeda et al.	

FOREIGN PATENT DOCUMENTS

Examiner/Initials	Cite No.	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	76
		Country Code ³	Number ⁴ , Kind Code ⁵ (if known)				

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¹ Applicant's unique citation designation number (optional). ² See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP 801.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST 3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language translation is attached.

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PTO/IS/B08A (10-01)

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	10/664,803
		Filing Date	September 19, 2003
		First Named Inventor	Unchalee Kositprapa
		Art Unit	
		Examiner Name	
Sheet 2 of 5	Attorney Docket Number	141-424	

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
T.A.S.	AU	US-5,955,106	09-21-1999	Moeckel et al.	
	AV	US-6,011,049	01-04-2000	Whitcomb	
	AW	US-6,031,004	02-29-2000	Timmins et al.	
	AX	US-6,099,859	08-08-2000	Cheng et al.	
	AY	US-6,153,632	11-28-2000	Rieveley	
	AZ	US-6,191,162	02-20-2001	Byrd et al.	
	BA	US-6,248,363	06-19-2001	Patel et al.	
	BB	US-6,291,495	09-18-2001	Rieveley	
	BC	US-6,296,874	10-02-2001	Cytie et al.	
	BD	US-6,329,403	12-11-2001	Odaka et al.	
	BE	US-6,383,471	05-07-2002	Chen et al.	
	BF	US-6,403,121	06-11-2002	Adjei et al.	
	BG	US-2002/0071866	06-13-2002	Geerke	
	BH	US-6,451,342	09-17-2002	Adjei et al.	
	BI	US-6,475,521	11-05-2002	Timmins et al.	
	BJ	US-6,524,621	02-25-2003	Adjei et al.	
	BK	US-2003/0113371	06-19-2003	Dhawan et al.	
	BL	US-2003/0118647	06-26-2003	Seth	
	BM	US-2003/0118649	06-26-2003	Gao et al.	
	BN	US-6,599,284	07-29-2003	Faour	

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T.A.S.	CA	WO 96/09823	04-04-1996	Luo et al.	
	CB	WO 98/11879	03-26-1998	Shell et al.	
	CC	WO 98/55107	12-10-1998	Shell et al.	
	CD	WO 99/47128	09-23-1999	Timmins et al.	
	CE	WO 99/55320	11-04-1999	Nishii et al.	
	CF	WO 00/28989	05-25-2000	Lewis et al.	
	CG	WO 00/72827	12-07-2000	Straub et al.	
	CH	WO 01/35940	05-25-2001	Lewis et al.	
	CI	WO 01/35941	05-25-2001	Lilliot et al.	
	CJ	WO 01/82875	11-08-2001	Cutie et al.	

Examiner Signature	Date Considered
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	10/664,803
		Filing Date	September 19, 2003
		First Named Inventor	Unchalee Kositprapa
		Group Art Unit	
		Examiner Name	
Sheet 4	of 5	Attorney Docket Number	141-424

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials ¹	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
/A.S./	DA	P. Karttunen et al., International Journal of Clinical Pharmacology, Therapy and Toxicology, "The pharmacokinetics of metformin: a comparison of the properties of a rapid release and a sustained-release preparation" Vol. 21, No. 1 - 1983, pp. 31-36.	
	DB	P.J. Pentikainen, International Journal of Clinical Pharmacology, Therapy and Toxicology, "Bioavailability of metformin. Comparison of solution, rapidly dissolving-tablet, and three-sustained-release-products", Vol. 24, No. 4 - 1986, pp. 213-220.	
	DC	Finnish Monograph of the Diiformin®, Retard tablet, with English translation	
	DD	O.J. Lucis, MD, Ph.D., MSC, Canada Medical Association J. Pharmacologic Update "The status of metformin in Canada" Vol. 128, January 1, 1983, pgs. 24-26.	
	DE	G. Belcher and D.R. Matthews Experiment and Clinical Endocrinology & Diabetes, "Safety and tolerability of pioglitazone" Suppl. 2 (2000) pgs. 267-273.	
	DF	Daniel Einhorn, MD et al., Clinical Therapeutics "Pioglitazone Hydrochloride in Combination with Metformin in the Treatment of Type 2 Diabetes Mellitus: A Randomized, Placebo-Controlled Study", Vol. 22, No. 12, 2000 pgs. 1395-1413.	
	DG	National Institute for Clinical Excellence Technology Appraisal Guidance - No. 21, "Guidance on the Use of Pioglitazone for Type 2 Diabetes Mellitus" March 2001, pgs. 1-13.	
/A.S./	DH	The Pharmaceutical Journal, Vol. 265, No. 7122, p. 710 November 11, 2000 Clinical (abstract only).	

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(use as many sheets as necessary)

Sheet	5	of	5
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Complete if Known

Application Number	10/664,803
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First Named Inventor	Unchalee Kositprapa
Group Art Unit	
Examiner Name	
Attorney Docket Number	141-424

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

English

Examiner
Signature

/Aradhana Sasan/

Date
Con

03/17/2008

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